UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/724,774	12/02/2003	Warren Finlay	034343-2	9435

22204 7590 06/14/2005

NIXON PEABODY, LLP
401 9TH STREET, NW
SUITE 900
WASHINGTON, DC 20004-2128

EXAMINER	
BUNIN, ANDREW M	

ART UNIT	PAPER NUMBER
3743	

DATE MAILED: 06/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/724,774	FINLAY ET AL.	
	Examiner	Art Unit	
	Andrew M. Bunin	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12/02/03* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the powder source claimed in claim 1 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the longitudinal flow and secondary flow claimed in claim 1 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the straight diffuse claimed in claim 9 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional

replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Britto et al. (US 6098619). Britto et al. discloses a device for deagglomerating powder agglomerates that has a chamber 68 adapted for fluid circulation. In addition, Britto et al. discloses an inlet 18 connected to the chamber and to a powder source where the powder agglomerates are entrained in a flow of gas. In figures 7 and 8, the chamber displays a powder source 62 and since the inlet 18 is adjacent to the powder source in the chamber, the inlet 18 is connected to this powder source. The flow of gas defines a swirling fluid flow inside the chamber where the powder agglomerates being subjected to at least one of turbulence, shear force fluidizing, collisions with other ones of the powder agglomerates, and

collisions with a surface of the chamber as shown in figures 7 and 8. Britto et al. continues to disclose an outlet 20 connected to the chamber 68 for inhalation such that the swirling fluid flow in the chamber 68 can exit from the chamber 68 as a longitudinal fluid flow and secondary fluid flow. In figure 8, the middle arrow at the outlet is designated the longitudinal flow and either one of the other arrows seem to curve away from the longitudinal axis of the middle area. Therefore, these two arrows are designated as the second fluid flow. Britto et al. includes a mesh D in the outlet 20 for preventing powder agglomerates above a predetermined size from traversing the mesh, and for reducing the secondary fluid flow relative to the longitudinal fluid flow exiting from the chamber. This is shown in figures 7 and 8 where the two secondary don't extend as far as the middle arrow (longitudinal flow). In addition, the mesh D is positioned near a base of the outlet 20 that is adjacent to the surface of the chamber so that most of the powder agglomerates in the chamber collide with the mesh at an oblique angle. Since the powder is being spun around in a vertical flow, these particles will collide with the mesh at an oblique angle.

As for claim 3, the chamber 68 is a cyclone chamber having a disc-shaped portion, the inlet 18 having a longitudinal axis that is perpendicular with respect to the longitudinal axis of the outlet as shown in figures 1 and 2. A disc is defined as a circular object or plate (dictionary.com). Therefore, figure 8 displays a disc shape. The axis of the inlet 18 is offset from the longitudinal axis of the outlet 20 so that an inner surface at the base of the inlet 18 is tangential with respect to the surface of the chamber 68. The two inlets 18 are offset in figure 5 since both

ports are off center from the outlet port 20. Therefore, the axes of the inlets 18 are both offset from longitudinal axis of the outlet 20.

Claims 7 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Britto et al. Britto further discloses a mouthpiece having a first end 14 being connectable to the outlet 20 and a second end 38 being insertable in the mouth of the user as shown in figure 3. In addition, the mesh D is connected to the first end 14 of the mouthpiece.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Britto et al. Although it isn't disclosed that the mesh has a pore size of less than 250 um or a pore size of the mesh ranging between 30 to 150 um, it would have been obvious to one having ordinary skill at the time of the invention to vary the design disclosed by Britto et al. to fit these ranges in order to meet the needs of different patients. It is crucial for a medication to be placed at certain locations in the lungs depending on the drug's purpose. Therefore, the size of the powder will vary depending on where it is supposed to be placed in the lungs. Smaller sized powder particles move further into the lungs, therefore, the size of the

mesh pore would be varied in order to deagglomerate the powder to a desired size. In addition, Britto et al. states, "particles suitable for respiration have an aerodynamic diameter between 0.5 and 10 um." (column 7, lines 5-7) Therefore, the mesh pore size must be at least less than 250 um to meet this range.

Britto also doesn't disclose the inlet 18 having an internal diameter of 5 to 7 mm and the outlet 20 having an internal diameter of 8 to 12 mm. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to vary the diameter sizes of the inlet and outlet because Applicant has not disclosed that an inlet internal diameter of 5-7 mm and an outlet internal diameter of 8-12 mm provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the diameter used for Britto et al. device because the diameter may be varied for patients of different ages or for different drug purposes. Depending on the drug, the diameter of the outlet and/or inlet would need to be a certain size to limit the amount of medication delivered as well as vary the speed at which the medication leaves the outlet. Therefore, it would have been obvious matter of design choice to modify Britto et al. to obtain the invention as specified in claim 6.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Britto et al. Although Britto et al. doesn't directly disclose a mouthpiece including a straight diffuser with a 13 to 15 degrees deflection. A diffuser can be considered a type of baffle; therefore, the sections 34 or section 38 would function as a diffuser with a 13-15 degree deflection. The internal diameter of

15-25 mm and length of 5-25 mm would be considered an obvious matter of design choice to a person of ordinary skill in the art at the time of the invention to vary the diameter and length of Britto et al. device to fit these ranges because Applicant has not disclosed that mouthpiece having an internal diameter of 15-25 mm and length of 5-25 mm provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with a variety of diameter and lengths depending on the patient's mouth size because changing the length or diameter can depend on the whether the patient is an adult, child, or infant as well as the medicament used can depend on the mouthpiece having a certain diameter.

Claims 10-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Britto et al. These method steps would have been obvious to one having ordinary skill in the art at the time of the invention since they would have resulted in the use of the device disclosed by Britto et al. as explained in the rejections above.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: US 6029661, US 6427688, US 6748947, and US 4940051

AMB
6/10/05

Henry Bennett
Supervisory Patent Examiner
Group 3700